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Medical Research Governance in Korea: The New Bioethics and Biosafety Amendment Bill (Draft 17-8353), or 'Inertia Reiterated'

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Abstract

This analysis is an update of last issue's article entitled "A Tale of Two Standards: Drift and Inertia in Modern Korean Medical Law" (SCRIPTed 5:2). After publication, a new Bioethics Amendment Bill (Draft 17-8353) was immediately introduced in Korea.

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1. Introduction

The law must move. It cannot be an objective, or a thing achieved. It is rather a journey, or a thing continually contemplated – a work in progress. It must constantly be in motion if it is to address the past, speak to the present, and remain relevant into the future. Indeed, it has been noted time and again, from the landmark 'persons case' in Canada,[1] to more contemporary claims in the technology context,[2] that the law must adapt, respond and thereby evolve, and it must not be left to stultify. The law simply cannot afford to stand still. And indeed the law does move and grow, albeit often in a reactive sort of way.

By way of example, Korea has experienced a brief period of high turnover of ideas and reform proposals in the medical law field, which is undergoing a significant transformation in both the clinical and research settings as a result of technological innovations.[3] However, just as it seemed a new research regime had been agreed through the combination of the *Bioethics and Biosafety Amendment Bill*[4] and the *Reproductive Cells Utilisation and Supervision Bill*,[5] politics intervened. These proposals, which had been identified by the Ministry of Health, Welfare and Family Affairs (MOHWFA) as legislative priorities, were abandoned when the 17th National Assembly was ended; and the 'wholesale amendment' of a legal regime that had failed so dramatically to curb the excesses and dishonesty of the immediately preceding 'Hwang era' was abandoned with them.

However, as claimed above, the law cannot and does not stand still, and everyone knew that the Korean law governing medical research could not afford to remain unchanged. In place of the abandoned Bills, a new *Bioethics Amendment Bill* (Draft 17-8353) was immediately introduced in Korea. Ultimately adopted and coming into force on 6 December 2008, Draft 17-8353 is not a new Act, but rather an Act to amend the existing (old) Korean *Bioethics and Biosafety Act 2005* (BBA 2005).[6] As such, the BBA 2005, albeit in amended form, retains its pre-eminent position (i.e. it remains the font of authority when it comes to medical research). In this short piece, we highlight the content of the BBA 2005, and then analyse very briefly the changes that Draft 17-8353 has rendered to the BBA 2005, considering whether this new

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[1] *Edwards v Canada (Attorney General)*, [1930] AC 124 (PC), a case which enunciated the 'living tree' doctrine for Canadian Constitutional interpretation, which has been fairly consistently applied and extended to the Canadian Charter of Rights: see *Reference re s 94(2) of the BC Motor Vehicle Act*, [1985] 2 SCR 486.

[2] See the comments of R Susskind, *The Future of Law: Facing the Challenges of Information Technology* (Oxford: OUP, 1998), or L Lessig, *Code: Version 2.0* (NY: Basic Books, 2006).

[3] Recall the flurry of recent medical law reform efforts considered in S Harmon & NK Kim, "A Tale of Two Standards: Drift and Inertia in Modern Korean Medical Law" (2008) 5:2 SCRIPTed 267-293.

[4] Draft No. 17-7702, 6 November 2007.

[5] Draft No. 17-7703, 6 November 2007.

[6] Law No. 7150, adopted 29 January 2004, last previous amendment March 2005.

regime in any way alters the conclusions previously advanced in SCRIPTed with respect to the trajectory of medical research governance in Korea.[7]

2. The Korean Bioethics and Biosafety Act 2005 and Draft 17-8353

A function of its uneasy birth at the competing hands of the MOHFA and the Ministry of Science and Technology,[8] the BBA 2005 pursued the dual purpose of promoting biotech development, on the one hand, and protecting human dignity and safety on the other.[9] Within that overall objective, it addressed the following issues:

- establishment of a National Bioethics Committee (NBC): ss 6-8;
- creation of Institutional Review Boards (IRBs) by research institutions: ss 9-10;
- MOHWFA oversight of research institutions: ss 18-21, 38-44, and 47;
- conduct of cloning: ss 11 and 22-23;
- production of chimeras: s 12;
- production of embryos, and their storage, use and disposal: ss 13-17, 20 and 21;
- conduct of DNA testing: ss 24-30;
- conduct of DNA banking and protection of genetic information: ss 31-35;
- conduct of gene therapy: ss 36-37; and
- imposition of sanctions for breaches of the rules: ss 49-55.

Draft 17-8353 alters or clarifies the boundaries of legal conduct with respect to several of these issues, and the remainder of this short article considers the old and new positions with respect to (1) core definitions and principles, (2) permissible research and conduct, (3) participant protections and (4) ethical oversight and enforcement.

2.1 Core Definitions and Principles

Although the BBA 2005 directs researchers to endeavour to safeguard human dignity and to carry out their work in accordance with the principles of bioethics and biosafety,[10] it contains no explicit reference to any mid-level guiding principles, nor to any relevant international instruments. It does state that care must be exercised when storing, handling and disposing of remaining embryos, and that research must be halted or appropriate measures taken when research poses a significant or potential

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[7] As offered in S Harmon and NK Kim, note 3.

[8] The BBA 2005 was preceded by some twelve aborted attempts by various factions within the Korean legislative community to introduce legislation: see S Han *et al.*, "New Cloning Technologies and Bioethics Issues: The Legislative Process in Korea" (2003) 13 Eubios JAIB 216-219.

[9] See ss 1 and 4, BBA 2005, and see both S Harmon & NK Kim, note 3, and HK Kim, "Bioethics and Biosafety Law in Korea" (2004) 13 *Journal of the Association of Policy Studies*, 45-71, who argue that the National Assembly attached more importance to the development of biotechnology than to its ethical control.

[10] See s 4, BBA 2005.

threat to bioethics or biosafety.[11] Nevertheless, there is no elucidation of the standards entailed by which bioethics or demanded for biosafety. Draft 17-8353 adds almost nothing to our understanding of the core principles or standards of bioethics in Korea, its only new provision being a reference to anonymisation of genetic information in DNA banks.[12] Although this constitutes an important privacy protection, it was envisioned in some quarters as having the effect of vitalising the DNA bank.

2.2 Permissible Research and Conduct

There are three primary areas of research and conduct that are addressed in the BBA 2005, namely embryo and reproductive research, stem cell research, and DNA banking.

With respect to embryos, the BBA 2005 states that no embryo shall be produced other than for the purpose of pregnancy (with the consequence that no artificial insemination shall be undertaken for research purposes).[13] However, embryos can be stored for up to 5 years (with the consent of the originators), after which they must be destroyed, unless they are to be used for research, in which case they must be pre-primitive streak and the research must be aimed at developing contraception and infertility treatments, curing rare or incurable diseases as decreed by the President, or otherwise be approved by the President after review by the NBC.[14] The BBA 2005 clearly prohibits reproductive cloning and stipulates that no one shall conduct Somatic Cell Nuclear Transfer (SCNT) other than for research aimed at curing rare or currently incurable diseases, as decided by the President after review by the NBC.[15] Although the BBA 2005 prohibits the implantation of an animal's somatic cell nucleus into a human oocyte whose nucleus has been removed,[16] it does not prohibit the implantation of a human nucleus into an animal oocyte. Draft 17-8353 rectifies this lacunae, amending s 12 to now clearly prohibit nuclear transfer between humans and animals.[17] Additionally, Draft 17-8353 redefines SCNT, limiting it to the transfer of a human somatic cell nucleus to a human oocyte from which the nucleus has been removed.[18]

With respect to stem cells more specifically, both the production and importation of stem cell lines are permitted in Korea, and some administrative standards have been erected around these processes. For example, Draft 17-8353 states that those who

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[11] See s 21, BBA 2005.

[12] See s 35-3(1), Draft 17-8353. By contrast, s 4 of the now abrogated *Reproductive Cells Utilisation and Supervision Bill* explicitly articulated the right of self-determination, stating that it applies to decisions about whether to allow reproductive cells to be extracted or donated or used to produce embryos. Matters of anonymisation certainly fall within the principle of self-determination, but explicit articulation of the underlying principle itself offers greater scope for protection insofar as it could support further protections and empowerments.

[13] See s 13, BBA 2005.

[14] See ss 16, 17 and 24, BBA 2005.

[15] See ss 11, 22 and 23, BBA 2005.

[16] See s 12(2), BBA 2005.

[17] Similarly, s 23 of aborted Bill 7702 also prohibited nuclear transfer between species.

[18] See s 2-4, Draft 17-8353.

produce or import stem cell lines must register with the Minister of Health, must obtain IRB approval if those stem cell lines are to be offered for research, must offer them free of any charge beyond the costs associated with their storage and must apprise the Minister of the present status of the stem cell lines (i.e. inform the Minister which lines are on offer at any given time).[19] With respect to the research itself, Draft 17-8353 stipulates that stem cell research must be directed at diagnosis, prevention or treatment of diseases, furthering understanding of the characterisation and specialisation of stem cells, or some other purpose which is deemed acceptable by Executive Order.[20] This latter provision in particular clarifies the purpose for which stem cell research can be undertaken, adopting broad and inclusive purposes. Finally, any research employing stem cells must undergo prior IRB consideration, report the outcome of that deliberation to the Minister of Health, submit a plan form utilising the stem cells to the provider of the stem cells, and must comply with the chief of the research institution, who is tasked with ensuring that research conforms to the research plans submitted.[21]

Finally, as noted above, the BBA 2005 addresses the creation of DNA banks and Draft 17-8353 states that both local and national support will be made available for the management of these banks,[22] though little is said about what form this support might take. Additionally, it states that genetic information held in banks must be anonymised, and the custodian of the bank must ensure the security and privacy of information. Further details relating to management, custody and custodial duties are created by Executive Order of the MOHWFA.[23]

2.3 Participant Protections

Protections for those participating in research are contained in provisions which address payment, consent and anonymisation of information.

Section 13 of the BBA 2005 states that no one shall provide sperm or oocytes for the purpose of financial reward,[24] presumably trying to avoid coercive situations engendered by poverty. Draft 17-8353 adds nothing to this general protective provision

Section 15 of the BBA 2005 states that institutions which collect sperm or oocytes shall obtain written consent from donors, patients and spouses. Draft 17-8353 makes a number of amendments to this section with respect to egg donation procedures. First, it stipulates that the medical institution which produces the embryo must first perform a medical examination of the egg donor, and it cannot extract eggs from a woman whose health falls within certain criteria set by the MOHWFA.[25] Second, the frequency of egg extractions that any single woman can undergo is to be set by

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[19] See ss 20-2 and 20-3, Draft 17-8353.

[20] See s 20-4(1), Draft 17-8353, which amends s 20 of the BBA 2005.

[21] See s 20-4, Draft 17-8353.

[22] This is achieved through an amendment to s 35 of the BBA 2005.

[23] See s 35-3, Draft 17-8353.

[24] See s 13, BBA 2005.

[25] See s 15-2, Draft 17-8353.

Executive Order.[26] Finally, the actual expenses associated with the egg donation (e.g. compensation for the time relating to the operation and recovery, as well as transportation costs) are compensable to the egg donor.[27] Although these are useful additions, they go nowhere near as far as the provisions of the now abrogated *Reproductive Cells Utilisation and Supervision Bill*, which explicitly stated that cell donors (and his/her spouse) must be sufficiently informed about the potential side-effects and consequences of extraction and/or donation, and that egg donors must be over 20, independent, and both physically and psychologically healthy.[28]

With respect to protection of patient privacy, as noted above, Draft 17-8353 makes an addition to s 35 of the BBA 2005, stipulating that, in the DNA banking context, all collected samples and genetic information must be anonymised. Again, however, it does not specify how the anonymisation will be achieved, what security measure will be expected, whether the information could, in future, be de-anonymised, and what the consequences of a security failure in this respect might be.

2.4 Ethical Oversight and Enforcement

The BBA 2005 calls for the establishment of a National Bioethics Committee (NBC), which is to review matters implicating bioethics and biosafety, including policies, research projects on remaining embryos or involving SCNT, DNA test prohibitions, gene therapy target diseases, and other issues of social or moral significance implicated by life sciences research.[29] Formed some three months after the BBA 2005 came into force,[30] it has never been clear whether the NBC is intended to be a policy advisory committee or a research oversight committee, and the ambiguity is not rectified by Draft 17-8353.

Section 9 of the BBA 2005 calls for the establishment of IRBs. IRBs are to review all matters relating to (amongst other things) research undertaken by their host institute, including ethical and scientific validity, consent and safety measures. They must conduct a review where there is a serious threat or potential threat "to bioethics and biosafety" as a result of research. Of course, in practice, the IRBs proved utterly ineffective at performing their functions.[31]

Draft 17-8353 recognises this and therefore includes some provisions directed at broadening the scope of IRB protection and enhancing the effectiveness of IRBs. For example, it expands the list of institutions that must seek IRB approval before they can act, adding embryo production institutions, somatic cell embryo clone research

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[26] See s 15-3, Draft 17-8353. Note that the corresponding Executive Order has not yet been made.

[27] See s 15-4, Draft 17-8353.

[28] See ss 4 and 14, RCUSB.

[29] See s 6, BBA 2005.

[30] Pursuant to Presidential Decree No 18621, 30 December 2004.

[31] See A Han, "The Ethical and Regulatory Problems in the Stem Cell Scandal" (2007) 4 *Journal of International Biotech Law*, 45-68, and National Bioethics Committee, *Intermediate Report on the Ethical Problems of Dr Woo Suk Hwang's Research*, 2 February 2006.

institutions and genetic diagnosis institutions.[32] Additionally, it directs the Minister of Health to support the IRB framework by:[33]

- providing education for IRB members;
- establishing examinations for IRB members; and
- enacting an evaluation system for IRBs (i.e. assessing their actions).

The practical demands of achieving openness and of evaluating IRBs are to be defined and administered by Executive Orders of the Minister of Health.[34]

These provisions go some way to systematising IRB function, but still do little to improve the independence of IRBs with respect to their host institutions (which proved a problem in the Hwang era). Moreover, they remain disturbingly quiet as to what inspectorate procedures the MOHWFA must meet, what documents it might regularly rely on, or what standards of conduct it will impose on IRBs in exercising its oversight and issuing its Executive Orders. Additionally, as noted above, they fail to offer or define any ethical principles which IRBs can use as a touchstone. Finally, s 47 of the BBA 2005 remains unchanged insofar as it states that the MOHWFA may delegate part of its authority, including managing ERIs, to the heads of other institutions or to related special institutions or organisations.

Importantly, Draft 17-8353 amends s 52 of the BBA 2005 so that its punishments – sentences of up to three years' imprisonment or fines up to 30 million Korean won – are applicable to anyone who tempts, facilitates or mediates in providing or utilising sperm or eggs for monetary reward, capital gain, or other personal benefits,[35] or who actually buys or sells sperm or eggs.[36] Draft 17-8353 also makes failing to perform a proper medical examination of the egg donor and failing to obtain proper informed consent (as defined by the BBA 2005) offences subject to imprisonment of up to two years and/or fines up to 30 million Korean won.[37]

3. Conclusion

Readers will recall our previous conclusion that reform efforts in the Korean medical research setting (e.g. Bill 7702 and the *Reproductive Cells Utilisation and Supervision Bill*) represented some improvement over the old regime, but evinced a certain "inertia" insofar as they clung to the desire to promote biotechnology and not unduly hinder biotech development.[38] In short, the balance achieved between biosafety promotion and reproductive health, on the one hand, and biotech promotion, on the other, remained skewed in the direction of the latter. The amendments that have now finally been adopted in Draft 17-8353 represent an equally modest renovation of the

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[32] See s 9(1), Draft 17-8353.

[33] See s 10-2, Draft 17-8353.

[34] See s 10-2(3), Draft 17-8353.

[35] See s 51-5, Draft 17-8353, which provision already existed in the BBA 2005.

[36] See s 51-6, Draft 17-8353.

[37] See s 52-2, Draft 17-8353.

[38] For our previous conclusions on legislative activities in the medical research setting, see S Harmon and NK Kim, note 3.

regime. Obviously, the provisions directed at greater systematisation and improvement of IRBs, and those directed at stiffening penalties for breaches, as well as expanding the failures against which they can be levelled, are an improvement. However, there is little to encourage faith that a new research governance era has dawned in Korea. Much will continue to depend on the actions of the IRBs and their host institutions and on the MOHWFA and the content and detail of the Minister of Health's Executive Orders. Of course, all of these actors failed spectacularly in their functions during the Hwang era – time and the generation of empirical evidence concerning oversight decisions will ultimately tell the tale.